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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/516,950	08/11/2005	Christopher J. Speirs	SPEI3002	1941

23364 7590 01/07/2009

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EXAMINER	
TRAN, SUSAN T	
ART UNIT	PAPER NUMBER
1615	

MAIL DATE	DELIVERY MODE
01/07/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/516,950	SPEIRS ET AL.	
	Examiner	Art Unit	
	S. Tran	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *4,6-25,30-35 and 39-42* is/are pending in the application.

4a) Of the above claim(s) *19-24 and 30-35* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *4,6-18,25 and 39-42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/28/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group I (claims 4, 6-18, 25 and 39-42) in the Suggested Restriction Requirement by applicant filed on 10/26/07 is acknowledged.

Claims 19-24 and 30-35 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the Suggested Restriction Requirement filed on 10/26/07.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 4, 6-14, 16, 25, 39 and 40 are rejected under 35 U.S.C. 102(b) as being anticipated by Heinicke et al. US 5,834,024.

Heinicke teaches a controlled release formulation comprising short and long lag pellets of diltiazem (abstract). The diltiazem core is coated with polymer or mixture of polymers such as Eudragit S, Eudragit L, or Eudragit L 30D (column 5, lines 24-44). The thickness of the coating is increasing or decreasing to obtain the desired short and long lag pellets (column 4, lines 21-38). Example 1 shows the short lag pellet comprises about 12% weight gained of the coating polymer, and the long lag pellet

comprises about 29% weight gained of the coating polymer. Heinicke further teaches the particle size of the pellet is about 1400 μm (example 1). The combined pellets are filled into capsule (column 6, line 64).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 4, 6-14, 16-18, 25, 39 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heinicke et al. US 5,834,024.

Heinicke is relied upon for the reason stated above. Heinicke does not explicitly teach the claimed coating weight gain of about 20%. Heinicke further does not teach the claimed ratio of the short and long lag pellets. However, it would have been obvious to one of ordinary skill in the art to, by routine experimentation determine a suitable coating weight gain, as well as the ration between the short and long lags depends in the release profile desired. This is because Heinicke teaches a controlled release dosage form effective to permit release of active agent at different cites in the GI tract over a 24 hours period, and because Heinicke teaches a weight gain of about 29%, with a mixture of 40% short lag and 60% long lag pellets (example 1).

Claims 4, 6-18, 25, 39-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Speirs US 5,834,021, in view of Andre et al. EP 1064938 A1.

Speirs teaches a controlled release dosage form comprising enterically coated pellet of prednisolone metasulphobenzoate incorporated into enterically coated capsule (abstract; and column 5, lines 61-67). Enteric coating polymer includes Eudragit S or Eudragit L (column 5, lines 9-34). The pellet has a diameter in the range of 700-1700 μm (column 4, lines 66-67). Spear further teaches that the thickness of the Eudragit coating on the pellets is between 15-30% based on the uncoated granule (column 5, lines 39-52).

Speirs does not expressly teach dosage form comprising plurality of particle with different release profiles.

Andre teaches a multiparticulate dosage form comprising active core, coating with film forming polymer such as Eudragit polymer (abstract; and paragraphs 0015-0017). Andre also teaches capsule comprising different population of coated multiparticulate dosage form with different release profiles (page 5, lines 38-43; and examples). Active agent includes prednisolone (paragraph 0024). Thus, it would have been obvious to one of ordinary skill in the art to modify the prednisolone dosage form of Speirs to prepare a dosage form with at least a timed pulse in view of the teachings of Andre. This is because Andre teaches that a timed pulse release dosage form allows targeting of a drug to a given site of the GI tract, in particular the colon (paragraph 0006), because Andre teaches a pulsed release dosage form that allows reduced dosing frequency, because Andre teaches a pulsed release dosage form suitable for

drugs including prednisolone, and because Speirs teaches the desirability to include a plurality of the coated pellets in a capsule for the delivery of prednisolone to the intestine (column 4, lines 38-43).

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to S. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on M-F 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. Tran/
Primary Examiner, Art Unit 1615